SESLHD POLICY COVER SHEET

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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director, Research
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FUNCTIONAL GROUP(S)	Research
KEY TERMS	Research, Ethics, Governance, Human Research Ethics Committee (HREC), South Eastern Sydney Local Health District (SESLHD), Collaborative Research Committee (CRC)
SUMMARY	A SESLHD specific research fee policy is to be used in conjunction and accordance to the most current- NSW Ministry of Health (MoH) Policy Directive PD2008_030 - *Human Research Ethics Committee (HREC) and Research Governance: Fee Policy for Review of Commercially Sponsored Research*

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SESLHD Research Fee Policy SESLHDPD/332

1. POLICY STATEMENT

A Fee Policy has been implemented in order to comply with NSW Ministry of Health (MoH) Policy Directive PD2008_030 - Human Research Ethics Committee (HREC) and Research Governance: Fee Policy for Review of Commercially Sponsored Research and provide a mechanism to fund the necessary operational and service improvement for the South Eastern Sydney Local Health District (SESLHD) and Human Research Ethics Committee (HREC) and Research Governance review to meet the NSW Office for Health and Medical Research (OHMR) Key Performance Indicators (KPIs).

2. AIMS

The policy has been implemented in order to ensure sufficient funds are available to deliver timely service that supports the activities of the SESLHD HREC and SESLHD Research and Governance Office. The policy is in alignment to the 2017-21 SESLHD Research Strategy objective to build research capacity in SESLHD, namely funding to support research within the LHD.

The funds supplement the supports provided by the SESLHD Research Office and are used to ensure quality governance and operational compliance (including salaries, administrative support and training) by the SESLHD HREC and Research Office to its obligations as directed by the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Research Involving Humans and the Australian Code for the Responsible Conduct of Research.

3. TARGET AUDIENCE

3.1 This policy applies to all researchers who submit documents to the SESLHD Research Office for review and approval to conduct research projects. This policy should be used in conjunction with the NSW Ministry of Health HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research (PD2008_030) or until otherwise instructed by NSW Ministry of Health.

3.2 A SESLHD Research office fee form must be completed with all relevant details before the application can be eligible for review by the SESLHD Research Office and SESLHD HREC.

3.3 Funding contributors to the SESLHD Collaborative Research Committee (CQC) once acknowledged on application, will be waivered of process fees.

3.4 There will be opportunity for case by case fee considerations at the discretion of Director, Research for exceptional cases.

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4. RESPONSIBILITIES

4.1 SESLHD Director: responsible for the overall governance and regulation of the fee structure within the SESLHD Research Directorate.

4.2 SESLHD Research Ethics & Governance Manager: responsible for the monitoring and measuring of the research application eligibility process and training of the staff. Shared responsibility for the exceptional case by case discretion of the fees and/or waiver of fees.

4.3 SESLHD Research Business Manager: responsible for the monitoring, measurement and reporting of the billing process, generated revenue and shared responsibility of the case by case discretion and/or waiver of the fees.

5. DEFINITIONS

SESLHD has adopted the definitions from the NSW Ministry of Health Policy Directive PD2011_006 - Clinical Trials - Insurance and Indemnity.

5.1 A commercially sponsored research project has the following characteristics:

5.1.1 It is initiated by a pharmaceutical/device company or other commercial entity and not by an investigator at a NSW public health service site.

5.1.2 The research is conducted to investigate a medication/device for commercial exploitation by its manufacturer/sponsor.

5.1.3 The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.

5.2 A sponsored (non-commercial) research project has the following characteristics:

5.2.1 The research must address relevant clinical questions and not pharmaceutical/device industry or commercial needs.

5.2.2 The sponsor (non-commercial) must declare any/in-kind support (e.g. provision of medicines, devices, funds) from any organisation.

5.2.3 The sponsor (non-commercial) must be the primary author and custodian of the clinical trial protocol

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5.3 Examples of groups that may fall under this category are;

5.3.1 Research institutes external to NSW Health;

5.3.2 Collaborative or cooperative research groups external to NSW Health

5.3.3 Universities.

5.4 An investigator initiated (SESLHD sponsored) research project has the following characteristics:

5.4.1 A pharmaceutical/device company is not acting as the Sponsor for the purposes of the CTN Scheme application.

5.4.2 A pharmaceutical/device company is not directly funding the conduct of the study that is making payment to the relevant hospital or investigator.

5.4.3 The clinical trial addresses relevant clinical questions and not industry needs.

5.4.4 The Principal Investigator and SESLHD is the primary author and custodian of the clinical trial protocol. Note – Investigator initiated trials can receive some industry funding or industry contribution, (e.g. educational grants, or supply of medication). However, the support must be declared in the protocol submission and *method of payment form* to ensure that the clinical trial retain its 'investigator initiated' status and fee levy reviewed.

5.5 Amendments to approved research

Fees are applied to each version change to Investigators Brochures (or equivalent) and protocol documents (or equivalent). No additional fee applies for Participant Information Sheet and Consent Forms (PISCFs) submitted in conjunction with an updated protocol or IB. However, if PISCFs are submitted separately, the fee applies.

Amendment definitions

5.5.1 *Complex*: Substantial changes to the project requiring review by the full HREC, e.g. Change of aims and objectives, addition of a sub-study or open-label extension which was not part of the originally approved protocol.

5.5.2 *Regular*: Most amendments fall into this category, e.g. IB updates, protocol revision to modify visit schedule, revision in risk section of PISCF following IB update, extension of follow-up from 3 to 5 years, addition of new questionnaire.

5.5.3 *Minor*: Correction of typographical errors without movement of text, update to contact details. Fee levy may be discussed with Research Manager.

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6. DOCUMENTATION

SOUTH EASTERN SYDNEY RESEARCH OFFICE – METHOD OF PAYMENT FORM

Please note that your submission will not be valid without correct completion of this form

Fund contributors to the SESLHD Collaborative Research Committee – do not require payment.

1. ADMINISTRATIVE DETAILS	
1.1.1 **DATE**	
1.1.2 **REFERENCE NUMBER** FOR ETHICS – YEAR/ETHXXXXX FOR GOVERNANCE – YEAR/STEXXXXX	
1.1.3 **STUDY TITLE**	
1.1.4 **ARE YOU OR THE PRINCIPAL INVESTIGATOR ON THIS PROJECT AN EXISTING RESEARCH FUND COMMITTEE MEMBER OR CONTRIBUTOR?** (I.E.: DO YOU MAKE DIRECT CONTRIBUTIONS THROUGH YOUR RFA ACCOUNT)	**YES** ☐ *Fund contributors (i.e.: from Restricted Fund Assets) - please fill in cost centre details below for verification -no payment will not be required.* **NO** ☐
1.1 PRINCIPAL INVESTIGATOR	
NAME	
EMAIL ADDRESS	
CONTACT NUMBER	
1.2 PERSON COMPLETING FORM	☐ NOT APPLICABLE: AS ABOVE
NAME	
EMAIL ADDRESS	
CONTACT NUMBER	

2. PAYMENT/INVOICE DETAILS	
2.1 **PAYMENT TYPE**	**INTERNAL RFA TRANSFER** ☐ **EXTERNAL FUNDING SOURCE** ☐
2.2 **INTERNAL RFA TRANSFER**	FUNDS WILL BE TRANSFERRED FROM COST CENTRE BELOW TO RESEARCH - 181333
2.2.1 **COST CENTRE NAME**	
2.2.2 **COST CENTRE NUMBER**	
2.2.3 **COST CENTRE SIGNATORY**	
2.3 **EXTERNAL FUNDING SOURCE**	INVOICES WILL BE DIRECTED TO THE NOMINATED PARTY BELOW
2.3.1 **Protocol Number**	
2.3.2 **FUNDING SOURCE NAME**	
2.3.3 **ABN** (IF APPLICABLE)	

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2.3.4 **ADDRESS**	
2.3.5 **CONTACT NAME**	
2.3.6 **CONTACT NUMBER**	
2.3.7 **CONTACT EMAIL**	

3.	**HREC/ETHICS APPLICATION SUBMISSION AND REVIEW FEES**	
3.1.1 **FUNDING CATEGORY**	**FEE**	**REQUESTED SERVICE**
3.1.2 **COMMERCIALLY FUNDED PROJECT** REGARDLESS OF AMOUNT	**$3,300**	**YES ☐**
3.1.3 **ADDITION OF SUB-STUDY TO RESEARCH PROJECTS WITH FULL COMMERCIAL FUNDING** SUB-STUDIES WILL BE REVIEWED AND FEE DETERMINED ON CASE BY CASE BASIS. THE HREC MAY REQUEST THE SUB-STUDY BE SUBMITTED AS A NEW APPLICATION AND CHARGE FULL FEE.	**$1665**	**YES ☐**
3.1.3 **COLLABORATIVE PROJECT WITH $50,000 OR MORE OF FUNDING**	**$3,300**	**YES ☐**
3.1.4 **COLLABORATIVE PROJECT WITH FUNDING UNDER $50,000**	**$150**	**YES ☐**
3.1.5 **INVESTIGATOR INITIATED PROJECTS FOR SESLHD STAFF *** INCLUDES STUDENTS	**$150**	**YES ☐**
3.1.6 **INVESTIGATOR INITIATED PROJECTS FOR EXTERNAL APPLICANTS**	**$300**	**YES ☐**

**SESLHD internal/external status open to discussion and the discretion of the Research Manager*

4.	**ETHICS AMENDMENTS – POST APPROVAL**	
4.1 **FUNDING CATEGORY**	**FEE**	**REQUESTED SERVICE**
4.1.1 **COMMERCIALLY FUNDED PROJECT** INCLUDES CHANGES TO PROTOCOL AND IB. PISCFs WILL BE CHARGED AS SEPARATE DOCUMENTS UNLESS THEY ARE SUBMITTED AS PART OF A PROTOCOL AMENDMENT	**$550** PER AMENDED DOCUMENT	**YES ☐**
4.1.2 **COLLABORATIVE PROJECT WITH $50,000 OR MORE OF FUNDING** SPONSOR BEING A RESEARCH INSTITUTE/UNIVERSITY/ OR OTHER COLLABORATIVE GROUP	**$550** PER AMENDED DOCUMENT	**YES ☐**
4.1.3 **COLLABORATIVE PROJECT WITH FUNDING UNDER $50,000**	**$100**	**YES ☐**
4.1.4 **INVESTIGATOR INITIATED PROJECTS**	**$100**	**YES ☐**

5.	**GOVERNANCE (SSA) APPLICATION SUBMISSION AND REVIEW FEES**	
5.1 **FUNDING CATEGORY**	**FEE**	**REQUESTED SERVICE**
5.1.1 **COMMERCIALLY FUNDED PROJECT**	**$3,740**	**YES ☐**
5.1.2 **COLLABORATIVE PROJECT WITH $50,000 OR MORE OF FUNDING**	**$3,740**	**YES ☐**
5.1.3 **COLLABORATIVE PROJECT WITH FUNDING UNDER $50,000**	**$500**	**YES ☐**
5.1.4 **INVESTIGATOR INITIATED PROJECTS** INCLUDES STUDENTS	**$150**	**YES ☐**

6.	**GOVERNANCE AMENDMENTS – POST APPROVAL**	
6.1 **FUNDING CATEGORY**	**FEE**	**REQUESTED SERVICE**
6.1.1 **COMMERCIALLY FUNDED PROJECT** INCLUDES CHANGES TO PROTOCOL, IB, PISCF, and CONTRACT VARIATIONS	**$500**	**YES ☐**

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6.1.2 **COLLABORATIVE PROJECT WITH $50,000 OR MORE OF FUNDING** SPONSOR BEING A RESEARCH INSTITUTE/UNIVERSITY/ OR OTHER COLLABORATIVE GROUP	**$500**	**YES ☐**
6.1.3 **COLLABORATIVE PROJECT WITH FUNDING UNDER $50,000**	**$100**	**YES ☐**
6.1.4 **INVESTIGATOR INITIATED PROJECTS**	**$100**	**YES ☐**

Disclaimer: This document is solely for use within South Eastern Sydney Local Health District and unauthorised dissemination or modification should not take place.

7. REFERENCES

- NSW Ministry of Health Policy Directive PD2008_030 – HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research
- NSW Ministry of Health Policy Directive PD2011_006 – Clinical Trials – Insurance and Indemnity
- SESLHD Research Strategy 2017-2021

8. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
August 2021	DRAFT	Initial draft by Marie Le Bechennec.
September 2021	DRAFT	Draft for Comments period. Feedback incorporated.
October 2021	DRAFT	Approved by Executive Sponsor. To be tabled at Clinical and Quality Council for approval.
December 2021	1	Approved at Clinical and Quality Council.

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